NIST HANDBOOK 150 CHECKLIST

Instructions to the Assessor: This checklist addresses the general accreditation criteria prescribed in NIST Handbook 150, *NVLAP Procedures and General Requirements* (2006 edition). The checklist items are numbered to correspond to the requirements found in Clauses 4 and 5, and Annexes A and B of the handbook. Items marked with ♦ indicate a change in requirements from the 2001 edition of NIST Handbook 150.

Place an "X" beside each checklist item that represents a nonconformity. Place a "C" beside each item on which you are commenting for other reasons. Record the item number and written nonconformity explanation and/or comment on the comment sheet(s) at the end of the checklist. Write "OK" beside all other items you observed or verified as compliant at the laboratory.

4 Management requirements for accreditation

4.1 Organization

OK **4.1.1** The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.

Organization Chart is part of QA 100
150-22 - 4.1.1 - QA 300, Par. 4.1 and QA 600, Par. 4.2.

Legal name of laboratory ownership: **InfoGard Laboratories, Inc.**

OK **4.1.2** It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this handbook and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.

Clause 4.1 -Introduction
150-22 - 4.1.2 - QA 500, Par. 4.2

OK **4.1.3** The management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

QA 600 - Test and Evaluation - Clause 4.13 - Off-Site Test and Evaluation. The organization has two buildings in their main facility in San Luis Obispo; about a block apart.

OK **4.1.4** If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.

QA 600 Clause 4.2 Impartiality and Independence and QA 100 , Clause 4.1 Introduction.

NOTE 1 Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this handbook.

NOTE 2 If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgement. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its testing or calibration activities.

4.1.5 The laboratory shall:

OK a) have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);

QA 100 , Clause 4.6.1 Organizational Structure plus the organizational chart

OK b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

Impartiality of temporary or contract employees clause 4.3 of QA400

OK c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

The "Confidential Information and Invention Assignment Agreement for Employee" form is Appendix I of QA 402 covers this subject. It is referred to in QA 400 Clause 4.2 as the "Non-Disclosure Agreement." The two descriptions refer to the same document. This issue was resolved on-site.

OK d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;

QA 400, Paragraph 4.2 requires new employees to sign an Impartiality Agreement. The Impartiality Agreement is Appendix VI of QA 402.

OK e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;

Paragraph 4.6.1 of QA 100 covers this. Also, Appendix I of QA 100 is the organizational chart showing the relationship between QM, technical operations, and support services.

OK f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;

QA 100, 4.6.3 through 4.6.8

OK g) provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;

QA 100, 4.6.3 through 4.6.8

OK h) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;

QA 100, Paragraph 4.6.3, General Manager Responsibilities

Name of person: **Tom Caddy**
Area of responsibility: **General Manager**
Repeat as necessary: **Ken Kolstad, Deputy General Manager**

OK i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;

QA 100, Paragraph 4.6.7 defines the Quality Assurance Responsibilities

Name of person: **Joan Lozano**

OK j) appoint deputies for key managerial personnel (see Note).

Deputy Quality Assurance Manager is Ken Kolstad.

Name(s): _____

OK♦ k) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

QA 100, paragraph 4.6.2; Also, 4.6.3 -through 4.6.8; Also, 4.5 - total quality management.

NOTE Individuals may have more than one function and it may be impractical to appoint deputies for every function.

OK♦ **4.1.6** Top management shall ensure that the appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

QA 100 - Paragraph 4.6.2 - Policy and Objectives, Second Paragraph

4.2 Management system

4.2.1

OK a) The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities.

QA 100 - Paragraph 4.1 and 4.2

OK b) The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results.

Paragraph 4.2 mentions the quality management system philosophy.

OK c) The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

QA 100 , Paragraphs 4.2, 4.3 and 4.4.
150-22 - 4.2.1 - QA 100, Par. 4.4

OK **4.2.2** The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management review.

Date of most recent quality manual: **February 26, 2007**

The quality policy statement shall be issued under the authority of top management. It shall include at least the following:

Paragraphs 4.3 and 4.4 of QA 100.

OK a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;

QA 100, par. 4.2

OK b) the management's statement of the laboratory's standard of service;

QA 100, par . 4.2

OK c) the purpose of the management system related to quality;

QA 100 4.2 - Total Quality Management

OK d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and

QA 100 - 4.6.8 -Project Staff Responsibilities

OK♦ e) the laboratory management's commitment to comply with this handbook and to continually improve the effectiveness of the management system.

QA 100 - 4.6.2 -Policy and Objectives. Reviewed Quality Meeting Attendance records on Quality. Meetings are held as necessary.
150-22 - 4.2.2 - Quality Manual, Table of Contents

NOTE The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents.

OK♦ **4.2.3** Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness.

QA 100, 4.5 Total Quality Management
150-22 - 4.2.3 - QA 611,
150-22 - 4.2.3 - a) - QA 611, Par. 5.2d
150-22 - 4.2.3 - b) - QA 611, Section 4
150-22 - 4.2.3 - c) - QA 611, Par. 5.3
150-22 - 4.2.3 - d) - QA 611, Appendix II
150-22 - 4.2.3 - e) - QA 600, Par. 4.2
150-22 - 4.2.3 - f) - QA 611, Par. 5.7.1 b
150-22 - 4.2.3 - g) - QA 611, Par.5.3.1
150-22 - 4.2.3 - h) - QA 500, Par. 4.2
150-22 - 4.2.3 - i) - QA 611, Par. 5.8.1 note
150-22 - 4.2.3 - j) - QA 611, Appendix II, Section 6

OK♦ **4.2.4** Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

QA 100, 4.2 and QA 100, 4.6.3 - General Manager Responsibilites.

4.2.5

OK a) The quality manual shall include or make reference to the supporting procedures including technical procedures.

QA 100, 4.3 and 4.4 are appropriate.

OK b) It shall outline the structure of the documentation used in the management system.

QA-100, 4.4 -Quality System of Documents.

OK **4.2.6** The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this handbook, shall be defined in the quality manual.

QA 100, 4.6.4 - Technical Representative Responsibilities and 4.6.7 - QA Manager Responsibilities.

OK♦ **4.2.7** Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

QA 100 - 4.4 - Quality System of Documents contains the sentence "approval managers will ensure that the integrity of the management system is maintained before approving any changes." QA 200 - Quality Assurance - Pargraph 4.7 - Change Control is essential for this requirement.

4.3 Document control

4.3.1 General

X The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.

QA 200, 4.7 - Change Control is appropriate.
Two documents were reviewed; both had the same header information but contained different information (QA201 procedure).

NOTE 1 In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.

NOTE 2 The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.13.

4.3.2 Document approval and issue

4.3.2.1

OK a) All documents issued to personnel in the laboratory as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue.

QA 200, 4.7 - Change Control is relevant; it references QA 100 (Paragraph 4.4 - Quality System of Documents) is also relevant.

OK b) A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

The Table of Contents is the Master List of documents in the quality manual. Paragraph 4.7 - change control of QA 200 covers the retrieval and destruction of

invalid or obsolete documents. A document destruction company is used on a monthly basis to assure safe and consistent destruction of obsolete documents.

4.3.2.2 The procedure(s) adopted shall ensure that:

OK a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;

QA 200, 4.7, Change Control covers this issue.

OK b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;

Internal audits are held annually and the documents are reviewed at that time. QA 201 Internal Audits is appropriate.

OK c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

QA 200, 4.7 is appropriate.

OK d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

QA 200, 4.7 is pertinent. A sample document was reviewed from the QA manager's files; it was appropriately marked in red ink as "old."

4.3.2.3 Management system documents generated by the laboratory shall be uniquely identified. Such identification shall include:

QA 100, 4.4 - Quality System of \Documents is appropriate.

OK a) the date of issue and/or revision identification,

The header of the controlled documents has the revision date, and the revision level listed.

OK b) page numbering,

The header of the conrolled documents has page x of y format where x is the page number and y is the total number of pages in the document.

OK c) the total number of pages or a mark to signify the end of the document, and

As above.

OK d) the issuing authority(ies).

The issuing authority is on the cover page of the controlled documents.

4.3.3 Document changes

OK **4.3.3.1** Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

QA 207 - Document Change Control is pertinent.

OK **4.3.3.2** Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.

IN 207-I \Document Change Notice Form is appropriate. Paragraph 2.1 g) - Description of Change covers the specific changes and the use of a "redlined document."

4.3.3.3

N/A a) If the laboratory's document control system allows for the amendment of documents by hand pending the reissue of the documents, the procedures and authorities for such amendments shall be defined.

All changes are electronic.

N/A b) Amendments shall be clearly marked, initialed and dated. A revised document shall be formally reissued as soon as practicable.

All changes are electronic.

OK **4.3.3.4** Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.

IN 207-I \Document Change Notice Form is appropriate. Paragraph 2.1 g) - Description of Change covers the specific changes and the use of a "redlined document."

4.4 Review of requests, tenders and contracts

OK **4.4.1** The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:

QA 1001 - Contract Review - Paragraphs 5.1 and 5.2 are appropriate. 5.1 covers the standard quotation case while 5.2 covers the non-standard quotation.

OK a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);

Appendix I of QA 1001 covers this in the "Contract Review Checklist."

OK b) the laboratory has the capability and resources to meet the requirements;

Appendix I of QA 1001 covers this in the "Contract Review Checklist."

OK c) the appropriate test and/or calibration method is selected and is capable of meeting the customers' requirements (see 5.4.2).

Appendix I of QA 1001 covers this in the "Contract Review Checklist."

OK d) Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the customer.

Appendix I of QA 1001 covers this in the "Contract Review Checklist."
150-22 4.4.1 - QA 1001, Appendix I and QA 1003, Appendix III

NOTE 1 The request, tender and contract review should be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account. For internal customers, reviews of requests, tenders and contracts can be performed in a simplified way.

NOTE 2 The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in interlaboratory comparisons or proficiency testing and/or the running of trial test or calibration programs using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.

NOTE 3 A contract may be any written or oral agreement to provide a customer with testing and/or calibration services.

OK **4.4.2** Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract.

The QA 1001 procedure was just released (2/21/07) and no contract has yet been

reviewed with this new procedure.
150-22 - 4.4.2 - QA 1003, Appendix III

NOTE For review of routine and other simple tasks, the date and the identification (e.g., the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for ongoing routine work performed under a general agreement with the customer, provided that the customer's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained.

OK **4.4.3** The review shall also cover any work that is subcontracted by the laboratory.

QA 1002 - Subcontracting is appropriate; there also is a question on the Contract Review Checklist that covers subcontracting (Appendix I of QA 1001).
150-22 - 4.4.3 - QA 600, Par. 4.2

OK **4.4.4** The customer shall be informed of any deviation from the contract.

Paragraphs 5.2.2 and 5.2.3 of QA 1001 are appropriate; both address changes to the contract statement of work from the Business Area Manager and the General Manager perspectives.
150-22 - 4.4.4 - QA 1003, Appendix III

OK **4.4.5** If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

QA 601 - Paragraph 5.1.4 is appropriate; the Project Manager may "inform the customer when requested or required tasks are out of scope of the work agreed upon with the customer as required by contract." Secondly, the project manager will "work approval and funding of out of scope tasks with the customer."

4.5 Subcontracting of tests and calibrations

OK **4.5.1** When a laboratory subcontracts work whether because of unforeseen reasons (e.g., workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g., through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this handbook for the work in question.

QA 1002 - Subcontracting is appropriate. Paragaraph 5.1.4 for the Business Area Manager states "review the the subcontract proposal and recommendation to ensue the subcontractor is accredited for the services identified in the statement of work." Also, Paragraph 4.12 of QA 600 (Test and Evaluation) covers criteria for the Voting System Testing Lab qualifications. It states that " if voting system core testing that is outside of InfoGard's scope of accreditation is subcontracted, the subcontracted laboratory must be located in the United States and must be accredited by NVLAP" LAP MUST BE DEFINED IN THE GLOSSARY TO COVER A2LA IN ORDER TO QUALIFY NTS. An agreement with NTS exists but it is covered in the QM.(QA1002). Resolved on site.
150-22 - 4.5.1 - QA 600, Par. 4.12

OK **4.5.2** The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.

Paragraph 4.12 of QA 600 covers this.
150-22 - 4.5.2 -QA 600, Par. 4.12

OK **4.5.3** The laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

Paragraph 4.12 of QA 600 covers this.
150-22 - 4.5.2 -QA 600, Par. 4.12

OK **4.5.4** The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this handbook for the work in question.

Paragraph 4.12 of QA 600 covers this.
150-22 - 4.5.4 -QA 600, Par. 4.4, Par. 4.7, and Par. 4.12

4.6 Purchasing services and supplies

OK **4.6.1** The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.

QA 800 is the Policy on Material Control and QA 801 is the Procedure on Purchasing; the two documents cover the purchase of materials (supplies). Procedure QA 1002 covers the purchase of services under 5.1 (subcontracting of test and evaluation services) and 5.2 (subcontracting of non-test and evaluation services).

4.6.2

OK a) The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements.

QA 802 - Procedure on Receiving covers this topic. It includes an Instruction (IN 802-II) which details how to complete a Receiving Inspection Report form which includes a question on "suitability for testing." Reviewed the latest entries on the receiving log and found them acceptable.

OK b) Records of actions taken to check compliance shall be maintained.

QA 802

OK **4.6.3** Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

QA 802 and IN 802-II are appropriate.

NOTE The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the management system standard under which they were made.

4.6.4

OK a) The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and

QA 1002 - Paragraph 5.1.4 specifies that the Vendor Pre-Qualification Form must be completed by the subcontractor for services.

___ b) shall maintain records of these evaluations and list those approved.

QA 1002 - Paragraph 5.1.5 - Quality Manager approves the subcontractor and under Paragraph 4.12 of QA 600, a "register of all subcontractors will be maintained and records of the subcontractor's compliance to the requirements of handbook 150 shall be maintained." The register of approved subcontractors is maintained by the Quality Assurance Manager under the responsibility item in 4.6.7 of QA 100 reading "maintain quality records."

4.7 Service to the customer

OK **4.7.1** The laboratory shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers.

QA 601 - paragraphs 5.1.3 (project communication) and paragraph 5.1.4 (project scope) cover this topic. Appendix 1 of QA 601 is a Running Status Report that is distributed to the customer on a weekly basis.

NOTE 1 Such cooperation may include:

a) providing the customer or the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the customer;

b) preparation, packaging, and dispatch of test and/or calibration items needed by the customer for verification purposes.

NOTE 2 Customers value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.

OK♦ **4.7.2** The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service.

QA 200 - 4.8 - Preventive Action specifies that "feedback, both positive and negative, from customers shall be solicited and documented." Also, QA 608 (Project Closeout Analysis) specifies that the business development manager has responsibility for conducting the cutomer satisfaction survey with the customer. Some sample customer satisfaction survey were reviewed and found to be acceptable.

NOTE Examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers.

4.8 Complaints

OK **4.8.1** The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties.

The policy is found in QA 200 (Quality Assurance) and covers complaints in paragraph 4.5 - Complaints. The procedure is found in QA 206 which is entitled "Complaints." QA 206 contains both a complaint log form and a complaints report form. The complaint log was reviewed and found to be completed as per the procedure.

OK **4.8.2** Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.11).

The complaint log was found to be current.

4.9 Control of nonconforming testing and/or calibration work

OK **4.9.1** The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that:

The policy for Non-Conforming Test or Evaluation Work is found in QA 600, paragraph 4.10. The appropriate procedure is QA 203 - Corrective Action Plan. The Corrective Action Plan log was reviewed and found to be well-documented and current.

OK a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified;

QA 600 - paragraph 4.10 covers this.

OK b) an evaluation of the significance of the nonconforming work is made;

QA 600 - paragraph 4.10 covers this.

OK c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work;

QA 600 - paragraph 4.10 covers this.

OK d) where necessary, the customer is notified and work is recalled;

QA 600 - paragraph 4.10 covers this.

OK e) the responsibility for authorizing the resumption of work is defined.

QA 600 - paragraph 4.10 covers this.

NOTE Identification of nonconforming work or problems with the management system or with testing and/or calibration activities can occur at various places within the management system and technical operations. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.

OK **4.9.2** Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 shall be promptly followed.

QA 600 - paragraph 4.10 covers this.

4.10 Improvement

OK♦ The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

QA 100 has a paragraph entitled Quality Commitment (4.2); it has a sub-paragraph that says "InfoGard Laboratories is committed to Total Quality Management (TQM) and has established a system of controls and feedback to continuously improve quality." Also, the same sentence is repeated in 4.5 (TQM) of QA 100.

4.11 Corrective action

4.11.1 General

OK The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.

QA 600 - Test and Evaluation is the Policy on this issue, especially Paragraph 4.10 (Non-Conforming Test or Evaluation Work). The last sentence of this paragraph states that "corrective action shall be immediately initiated when the evaluation indicates that the non-conforming work could recur or that the Quality System Policies or Procedures are not compliant or being followed." The Procedure is QA 203 (Corrective Action Plan) with special attention being paid to Paragraphs 5.1 and 5.2. IN 203-I is the Instruction on completing the Corrective Action Plan and it includes emphasis on looking for the Root Cause. Both the Corrective Action Plan Log and the Corrective Action Plans are kept in a notebook which was specifically reviewed and found to be acceptable.

NOTE A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from customers and from staff observations.

4.11.2 Cause analysis

OK The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

Covered in QA203 and IN 203-I;as described above.

NOTE Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.

4.11.3 Selection and implementation of corrective actions

OK a) Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Covered in QA203 and IN 203-I;as described above.

OK b) Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.

Covered in QA203 and IN 203-I;as described above.

OK c) The laboratory shall document and implement any required changes resulting from corrective action investigations.

Covered in QA203 and IN 203-I;as described above.

4.11.4 Monitoring of corrective actions

OK The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

QA 203, Paragraph 5.2 (Quality Assurance Manager), d) - "monitor the results of the corrective action taken to ensure it is effective."

4.11.5 Additional audits

OK Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this handbook, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.

QA 203, Paragraph 5.2 (Quality Assurance Manager), b) - "---. An internal audit of the appropriate areas of activity shall be performed."

NOTE Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.

4.12 Preventive action

4.12.1

OK a) Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified.

The appropriate policy is QA 200 (Quality Assurance) ; Paragraph 4.8 entitled Preventive Action.

OK♦ b) When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

The appropriate policy is QA 200 (Quality Assurance) ; Paragraph 4.8 entitled Preventive Action. The last sub-paragraph says " If preventive action is required, action plans shall be developed, etc."

OK **4.12.2** Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.

The appropriate policy is QA 200 (Quality Assurance) ; Paragraph 4.8 entitled Preventive Action. The last sub-paragraph says " Procedures for preventive actions shall include, etc."

NOTE 1 Preventive action is a proactive process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

NOTE 2 Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.

4.13 Control of records

4.13.1 General

OK **4.13.1.1** The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.

QA 200 on Quality Assurance covers Quality Records in Paragraph 4.6. QA 600 (Test and Evaluation) covers Test and Evaluation Records in Paragraph 4.8. QA 301 (Test and Evaluation Evidence Control) addresses Quality Document Control in Paragraph 4.2
150-22 - 4.13.1 -QA 900, Appendix I

4.13.1.2

OK a) All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

QA 900 on Records covers this area of interest in Paragraphs 4.4 (Retention) and 4.5 (Storage).

OK b) Retention times of records shall be established.

Record Storage and Retention times are covered specifically in QA 900, Appendix I which is a Record Storage and Retention Matrix. Note - The Minimum Length of Storage time for Voting Test Records is specified as 3 years in the present QA 900 documentation; this may change in the future as Election Assistance Commission rules are finalized and formalized.

NOTE Records may be in any media, such as hard copy or electronic media.

OK **4.13.1.3** All records shall be held secure and in confidence.

Paragraph 4.5 of QA 900 covers this with the statement "Records shall be stored such that they are protected from compromise."

OK **4.13.1.4** The laboratory shall have procedures to protect and back up records stored electronically and to prevent unauthorized access to or amendment of these records.

Paragraph 4.1 of QA 900 states that "computer based media properly identified, logged , and backed-up." Also, 4.1 atates "test and evaluation records shall be controlled and protected as customer proprietary information."
150-22 - 4.13.1 - QA 600, Par. 4.12

4.13.2 Technical records

4.13.2.1

OK a) The laboratory shall retain records of original observations, derived data and

sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period.

QA 600, Paragraph 4.8 (Test and Evaluation Records) is appropriate.

OK b) The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original.

QA 600, Paragraph 4.8 (Test and Evaluation Records) is appropriate

OK c) The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.

QA 600, Paragraph 4.8 (Test and Evaluation Records) is appropriate. "Records shall identify the personnel responsible for the test or evaluation and the date recorded."

NOTE 1 In certain fields it may be impossible or impracticable to retain records of all original observations.

NOTE 2 Technical records are accumulations of data (see 5.4.7) and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, customers' notes, papers and feedback.

OK **4.13.2.2** Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

QA 600, Paragraph 4.8 (Test and Evaluation Records) is appropriate
150-22 - 4.13.2 -QA 600, Par. 4.8

4.13.2.3

OK a) When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction.

QA 600, Paragraph 4.8 (Test and Evaluation Records) is appropriate

OK b) In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

QA 600, Paragraph 4.8 (Test and Evaluation Records) is appropriate
150-22 - 4.13.3 -QA 301, Par. 8.1 and Par. 9.3.1
150-22 - 4.13.4 -QA 600, Par. 4.7

4.14 Internal audits

4.14.1

OK a) The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this handbook. The internal audit program shall address all elements of the management system, including the testing and/or calibration

activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management.

Dates of most recent internal audit: February 23,2007

Note to assessor: Attach a copy of the full internal audit schedule.

QA 201 (Internal Audits) is the Quality System Procedure covering this topic. Reviewed the internal audit schedule for the year 2007. Also reviewed the latest internal audit report from February 23rd and found it acceptable. As a result of looking at the audit report, the document change notice ,DCN No. 122 (dated 27 February 2007), was reviewed and found to be acceptable. The Document Change Control procedure is QA 207 which covers the DCN process.

OK b) Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

Ken Kolstad does many of the audits as well as other trained personnel.
150-22 - 4.14.1 -QA 201, Par. 4.1 and QA 200, Par. 4.1

NOTE The cycle for internal auditing should normally be completed in one year.

OK **4.14.2** When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that the laboratory results may have been affected.

QA 201, Paragraph 5.3 d) assigns the Quality Manager an action item to generate a Corrective Action Plan (CAP) for quality discrepancies and departures from documented policies and procedures. QA 203 (CAP) assigns an action item to the Quality Assurance Manager to "monitor the results of the corrective action taken to ensure that it is effective." Finally, QA 600 (Test and Evaluation), paragraph 4.10 states that the program manager and the quality manager shall together determine whether to "notify the client."
150-22 - 4.14.2 -QA 201, Par. 4.1 and QA 200, Par. 4.1

OK **4.14.3** The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.

QA 201, Apendix I is the "Internal Audit Report Form" which outlines the audit summary, the discrepancies, and the CAP.
150-22 - 4.14.3 -QA 201, Par. 5.1, Notes.

OK **4.14.4** Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

QA 203, appendix I
150-22 - 4.14.4 -QA 201, Par. 5.1 and the Internal Audit Plan..

4.15 Management reviews

OK **4.15.1** In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements.

Date(s) of most recent management review: **February 2007**

What is the review schedule? **December - 2007**

The review shall take account of:

QA 200 (Quality Assurance) covers Management Reviews in paragraph 4.1. Details on the Management Reviews are found in QA 208 (Management Quality Review) especially Paragraph 5.2 (General Manager or Designee),

OK a) the suitability of policies and procedures;

QA 208 (Management Quality Review) highlights this.

OK b) reports from managerial and supervisory personnel;

QA 208 (Management Quality Review) highlights this

OK c) the outcome of recent internal audits;

QA 208 (Management Quality Review) highlights this

OK d) corrective and preventive actions;

QA 208 (Management Quality Review) highlights this

OK e) assessments by external bodies;

QA 208 (Management Quality Review) highlights this

OK f) the results of interlaboratory comparisons or proficiency tests;

QA 208 (Management Quality Review) highlights this

OK g) changes in the volume and type of the work;

QA 208 (Management Quality Review) highlights this

OK h) customer feedback;

QA 208 (Management Quality Review) highlights this

OK i) complaints;

QA 208 (Management Quality Review) highlights this

OK♦ j) recommendations for improvement;

QA 208 (Management Quality Review) highlights this

OK k) other relevant factors, such as quality control activities, resources and staff training.

QA 208 (Management Quality Review) highlights this
150-22 - 4.15.1 - QA 200 is the policy on Management Reviews and QA 208 is the procedure on "Management Quality Reviews." The record of Management Reviews was observed and found to be acceptable.

NOTE 1 A typical period for conducting a management review is once every 12 months.

NOTE 2 Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year.

NOTE 3 A management review includes consideration of related subjects at regular management meetings.

4.15.2

OK a) Findings from management reviews and the actions that arise from them shall be recorded.

The Management Review Reports were reviewed. The most recent one was February 23, 2007. There were actions agreed to at the management review with a timetable to accomplish the action items.

OK b) The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

The most recent Management Review report had "recommended actions" with a timetable to complete the "targeted tasks."
150-22 - 4.15.2 - As above.

5 Technical requirements for accreditation

5.1 General

5.1.1 Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from:

i) human factors (5.2);

ii) accommodation and environmental conditions (5.3);

iii) test and calibration methods and method validation (5.4);

iv) equipment (5.5);

v) measurement traceability (5.6 and Annex B);

vi) sampling (5.7);

vii) the handling of test and calibration items (5.8).

N/A **5.1.2** The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

N/A

5.2 Personnel

5.2.1

OK a) The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates.

QA 404 (Procedure on Employee Training) is pertinent. QA 400 is the policy on personnel and paragraph 4.5 on employee training states that "employees shall be provided training, as required, for performance of their job responsibilities."

OK b) When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

QA 100 (Quality System) specifies that the Business Area Manager has the responsibility to "ensure business area staff are adequately trained for their

respective business area tasks."
150-22 - 5.2.1 - QA 404, Paragraph 5.5 (VST Engineer Training - Business Area Manager) is appropriate, especially, c) "provide mentoring by a certified VST engineer for the nes Test Engineer to become adequately trained on the application fo the VSS 2002/2005 requirements to prepare for certification testing"

NOTE 1 In some technical areas (e.g., nondestructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the customer.

NOTE 2 The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have:

i) relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service;

ii) knowledge of the general requirements expressed in the legislation and standards; and

iii) an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned.

5.2.2

OK a) The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel.

QA 404, Paragraph 5.6 on Employee Continuation Training is appropriate.

OK b) The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel.

QA 400, Paragraph 4.5 on Employee Training is the policy. QA 404 is the procedure (Employee Training).

OK c) The training program shall be relevant to the present and anticipated tasks of the laboratory.

QA 404, Section 5 is the procedure that covers this topic

OK♦ d) The effectiveness of the training actions taken shall be evaluated.

QA 400, Paragraph 4.5 on Employee Training is the policy. QA 404 is the procedure (Employee Training) and it is covered in 5.1 b).
150-22 - 5.2.2 - QA 100, Appendix I calls out the personnel, their responsibilities and their reporting relationship in the organizational chart. Their responsibilites are specified in QA 100, Paragraphs 4.6.3 through 4.6.8.

5.2.3

OK a) The laboratory shall use personnel who are employed by, or under contract to, the laboratory.

QA 600, Paragraph 4.1 (Project Management) specifies "all test and evaluation projects shall have an InfoGard employee assigned as the Project Manager for the Project."

OK b) Where contracted and additional technical and key support personnel are

used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's management system.

QA 600, Paragraph 4.4, covers this item
150-22 - 5.2.3 - QA 100, Paragaph 4.3, states "Changes to the InfoGard Organization Chart, Apppendix I, must be communicated to NVLAP and EAC in writing within 30 days following the change.

OK **5.2.4** The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.

Reviewed the job description for the Quality Assurance Manager position and found it to be acceptable.
150-22 - 5.2.4 -QA 404, Par. 5.6. Reviewed the job folder, as above, and found it to be acceptable.

NOTE Job descriptions can be defined in many ways. As a minimum, the following should be defined:

i) the responsibilities with respect to performing tests and/or calibrations;

ok

ii) the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results;

ok

iii) the responsibilities for reporting opinions and interpretations;

ok

iv) the responsibilities with respect to method modification and development and validation of new methods;

ok

v) expertise and experience required;

ok

vi) qualifications and training programs;

Qualifications are listed.

vii) managerial duties.

ok

5.2.5

OK a) The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment.

QA 100, Quality System, Paragraphs 4.6.3, 4.6.4, and 4.6.6. cover this area.

OK b) The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel.

QA 404, Employee Training, Paragraph 5.6c covers "personnel shall maintain a record of training."

OK c) This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

QA 100, Paragraph 4.6.5 states that the personnel manager has responsibility for "maintaining personnel and training records for all employees."
150-22 - 5.2.5 - Covered in QA 404 (Employee Training), Paragraphs 5.1 and 5.5

(VST Engineer Training - Business Area Manager).
150-22 - 5.2.6 - QA 600, Paragraph 4.3 (Staff Training) covers this.
150-22 - 5.2.7 - QA 600, Paragraphs 4.4, 4.7 and 4.12 are appropriate.
150-22 - 5.2.8 - QA 100, Paragraph 4.6.5.
150-22 - 5.2.9 - QA 300, Paragraph 4.1 (Trusted Third Party Role) is pertinent.

NVLAP Note: This requirement also applies to Approved Signatories (see 1.5.2).

5.3 Accommodation and environmental conditions

5.3.1

OK a) Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.

QA 500, Paragraph 4.3 (Environment) is appropriate.

The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility.

QA 500, Paragraphs 4.3 and 4.4 (Off-Site Testing)

OK b) The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.

QA 500, Paragraph 4.3 (Environment) is appropriate
150-22 - 5.3.1 - QA 500, Paragraph 4.2 (Accommodations) and QA 600, Paragraph 4.13. (Off-Site Test and Evaluation).

5.3.2

OK a) The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned.

QA 500, Paragraphs 4.3 (Environment) and 4.4 (Off-Site Testing

OK b) Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

QA 500, Paragraph 4.4 (Off-Site Testing) covers this.
150-22 - 5.3.2 - QA 500, Paragraph 4.2 (Accommodations) is applicable.

OK **5.3.3** There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

QA 500, Paragraph 4.2 (Accommodation) covers this.
150-22 - 5.3.3 - QA 500, Par. 4.2, "Means shall be provided to protect the laboratory computer systems from viruses."

OK **5.3.4** Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.

QA 500, Par. 4.1 (Physical Access and Security) is appropriate.
150-22 - 5.3.4 - QA 500, Par. 4.2 - "The accommodations shall be adquate to provide separation between multiple products under simultaneous test or

			evaluation."
OK	**5.3.5**	Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.	
			QA 500, Par. 4.5 (Housekeeping) covers this. **150-22 - 5.3.5 - QA 600, Paragraph 4.13 (Off-Site Test and Evaluation) covers this.** **150-22 5.3.6 - QA 600, Paragraph 4.13 (Off-Site Test and Evaluation) covers this.**

5.4 Test and calibration methods and method validation

5.4.1 General

X	a)	The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.	
			QA 700 4.1. **QA 600 4.5. Methods and procedures developed or where procedural details and test artifacts or equipment need additional development and specification do not include consistently these factors. Examples are test methods for usability (HAVA 301 functional requirements), accessibility (validation of the procedures) to measure physical accessibility to identify setup conditions and effectiveness of the procedures.**
OK	b)	The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations.	
			QA 600. 4.11 Tool and Equipment use. Not identified for this program at this time. **QA 701, Test and Evaluation Tool control** **QA 610. FIPS 210 Test 5.1.7 Test Engineers, (example under other programs)**
OK	c)	All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3).	
			QA 600 4.5 Defer to 4.3. Checked in interviews
X	d)	Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.	
			QA 600 4.5 **Deviations entered in database record.** **QA 611. 5.1 Pre-Test phase product startup.** **This phase provides for reporting as a report but no indication that the client has accepted. A record of client acceptance is needed on variations.** **(150-22) 5.4.3 For the purposes of achieving product certification under HAVA, laboratories shall comply with interpretations of the test methods as provided by the EAC. When exceptions to the testing methodology may be necessary for technical reasons, the laboratory shall ask the EAC for an interpretation, the**

customer shall be informed, and details of an interpretation shall be described in the test report.
QA 611, 5.7/5.8 Laboratory shall ask the EAC for interpretation…..

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.

5.4.2 Selection of methods

C a) The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so.

Demonstrated in the use and adaption of Common Criteria methods, however, adaptation does not seem to be complete (see 5.4.1 and note) and several of the test methods reviewed looked like the details were copied due the emphasis on security to the exclusion of other operational factors such as accuracy and compliance with election law requirements

X b) When necessary, the standard shall be supplemented with additional details to ensure consistent application.

Examples missed are the setup of the election required to test for the alert and response on undervotes required in HAVA 301, identification of ballot layout criteria for accuracy and reliability testing, timing and sampling of ballot counting/voting during the accuracy (especially during 48 hr environmental testing where required), determining table height specification for the accessibility test of device controls for sets ups providing space and approach of wheel chair users.

OK c) When the customer does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated.

Example is the use of Common Criteria methods as base

OK d) The customer shall be informed as to the method chosen.

QA 611. 5.1 Pre-setup

OK e) The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.

QA 700, 4.3
Example VASSM 330, 6.5 Software automation validation. Others may need development

OK f) The laboratory shall inform the customer when the method proposed by the

customer is considered to be inappropriate or out of date.

QA 700, 4.3
QA 600, 4.5

5.4.3 Laboratory-developed methods

X a) The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.

QA 700, 4.2 Equipment Maintenance and Calibration provides one factor. Noted that existing test methods need review and futher work to consided factors described in the note below and in the list in 5.1.1.

OK b) Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.

QA 601. 5.1.3 Product communication (customer)

5.4.4 Non-standard methods

X a) When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration.

150-22 - 5.4.6 The laboratory shall clearly identify any test methods included in the test campaign that are outside of the laboratory's scope of accreditation. QA 611, 5.3.1.i Test Plan Generation. They "identify" the method is out of scope but statement needs to be strengthened to include reporting in test plan and report.

Needs to be added.

N/A b) The method developed shall have been validated appropriately before use.

No methods to assess.

NOTE For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information:

a) appropriate identification;

b) scope;

c) description of the type of item to be tested or calibrated;

d) parameters or quantities and ranges to be determined;

e) apparatus and equipment, including technical performance requirements;

Test election specification, pre-election setup and readiness checks, setup and methods for inducing and testing error conditions and responses, validation of test election counts

f) reference standards and reference materials required;

g) environmental conditions required and any stabilization period needed;

h) description of the procedure, including:

Missing or inadequate in previously described test methods

i) affixing of identification marks, handling, transporting, storing and preparation of items,

Covered by procedures for evidence

ii) checks to be made before the work is started,

Missing. Operational tests should specify what procedures or degree of readiness testing is completed: builtin pre-election diagnostics, standard pre-poll operations, Logic and Accuracy tests, Operational Status test are all choices

iii) checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,

See (ii)

iv) the method of recording the observations and results,

Good procedure in form of assertion database. However, see j) below

v) any safety measures to be observed;

i) criteria and/or requirements for approval/rejection;

Example, in accuracy and reliability test, procedures for handling and documenting errors that may not be disqualifying

j) data to be recorded and method of analysis and presentation;

Several of the methods need additional specification here

k) the uncertainty or the procedure for estimating uncertainty.

5.4.5 Validation of methods

5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

5.4.5.2

X a) The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.

Good examples of validation procedure but work still needs to be done to complete. Example, control code for source code review and induced errors.

X b) The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

Not done yet although policy and procedures and description of validation in the Source Code review, as an example, is valid.

NOTE 1 Validation may include procedures for sampling, handling and transportation.

NOTE 2 The techniques used for the determination of the performance of a method should be one of, or a combination of, the following:

i) calibration using reference standards or reference materials;

ii) comparison of results achieved with other methods;

iii) interlaboratory comparisons;

iv) systematic assessment of the factors influencing the result;

v) assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

NOTE 3 When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.

C **5.4.5.3** The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.

Good example in VSP 531 Reliability Test for adaptation for longer test to address potential requests for more rigorous reliability testing. Test Methods may need to specify the parameter ranges which may be needed to configurate the test and report in the test plan and final certification report

NOTE 1 Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.

NOTE 2 As method-development proceeds, regular review should be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized.

NOTE 3 Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g., accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

5.4.6 Estimation of uncertainty of measurement

C **5.4.6.1** A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.

Considered N/A for most voting system testing as values are expected to be discrete, deterministic but non-standard methods or later updates may introduce uncertainty of measurement

N/A **5.4.6.2** Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.

NOTE 1 The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

i) the requirements of the test method;

ii) the requirements of the customer;

iii) the existence of narrow limits on which decisions on conformity to a specification are based.

NOTE 2 In those cases where a well recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).

N/A **5.4.6.3** When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

NOTE 1 Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.

NOTE 2 The predicted long-term behavior of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.

NOTE 3 For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement (see 1.4).

NVLAP Note: ANSI/NCSL Z540-2-1997 and NIST Technical Note 1297, 1994 edition, are considered to be equivalent to the Guide to the Expression of Uncertainty in Measurement (GUM).

5.4.7 Control of data

OK **5.4.7.1** Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

OK a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;

QA 700, 4.1 Test and Evaluation Tools. No current cases

OK b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;

QA 301 Test and Evaluation Evidence Control: 6. Procedures

OK c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

QA 600, 4.5/4.11 Tool and Equipment Use. No equipment currently identifed

NOTE Commercial off-the-shelf software (e.g., word processing, database and statistical programs) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated as in 5.4.7.2 a).

5.5 Equipment

5.5.1

OK a) The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data).

QA 600, Paragraph 4.11 (Tool and Equipment Use) is appropriate. Also, QA 700, Paragraph 4.2 (Equipment Maintenance and Calibration) covers this item.

OK b) In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this handbook are met.

QA 600, Paragraph 4.12 (Outside Support Services and Supplies) is appropriate.
150-22 - 5.5.1 - QA 600, Par. 4.11 (Tool and Equipment Use) covers this item.

5.5.2

OK a) Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned.

QA 700, Par. 4.1 (Test and Evaluation Tools) and Par. 4.2 (Equipment Maintenance and Calibration) cover this item.

N/A b) Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results.

N/A

OK c) Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).

QA 700, Par. 4.2 (Equipment Maintenance and Calibration) cover this item.

		150-22 - 5.5.2 - QA 700, Par. 4.1 (Test and Evaluation Tools) covers this.
OK	**5.5.3**	Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.
		QA 600, Par. 4.11 (Tool and Equipment Use) and QA 700 , Par. 4.1 (Test and Evaluation Tools) cover this topic. **150-22 - 5.5.3 - QA 700, Paragraph 4.2 (Equipment Maintenance and Calibration) is appropriate and, also, QA 611 (Voting System Test Process), Par. 5.3.2 (Test Engineer) covers this topic.**
OK	**5.5.4**	Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.
		QA 700, Par. 4.1 (Test and Evaluation Tools) covers this. **150-22 - 5.5.4 - QA 700, Paragraph 4.2 (Equipment Maintenance and Calibration) is appropriate. QA 600, Par. 4.11(Tool and Equipment Use) also covers the topic.**
N/A	**5.5.5**	Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:
		No equipment at this time that requires calibration. **150-22 - 5.5.5 - QA 611 (Voting System Test Process), Par. 5.3.2 has a Note that covers this topic.**
N/A	a)	the identity of the item of equipment and its software;
OK	b)	the manufacturer's name, type identification, and serial number or other unique identification;
N/A	c)	checks that equipment complies with the specification (see 5.5.2);
N/A	d)	the current location, where appropriate;
N/A	e)	the manufacturer's instructions, if available, or reference to their location;
N/A	f)	dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
N/A	g)	the maintenance plan, where appropriate, and maintenance carried out to date;
N/A	h)	any damage, malfunction, modification or repair to the equipment.
OK	**5.5.6**	The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.
		QA 600, Par.. 4.11 (Tool and Equipment Use) covers this.

NOTE Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.

5.5.7

OK a) Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly.

QA 700, Par. 4.2 (Equipment Maintenance and Calibration) covers this.

OK b) The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 4.9).

QA 700, Par. 4.1 (Test and Evaluation Tools) handles this item.

OK **5.5.8** Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

QA 700, Par. 4.1 (Test and Evaluation Tools) handles this item in conjunction with QA 700, Par. 4.2 (Equipment Maintenance and Calibration).

OK **5.5.9** When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

QA 700, Par. 4.1 (Test and Evaluation Tools) handles this item.

OK **5.5.10** When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.

QA 700, Par. 4.2 (Equipment Maintenance and Calibration) covers this.

OK **5.5.11** Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g., in computer software) are correctly updated.

QA 700, Par. 4.2 (Equipment Maintenance and Calibration) covers this.

OK **5.5.12** Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.

QA 700, Par. 4.2 (Equipment Maintenance and Calibration) covers this.

5.6 Measurement traceability

5.6.1 General

OK a) All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service.

QA 700, Par. 4.2 (Equipment Maintenance and Calibration) covers this.

OK b) The laboratory shall have an established program and procedure for the calibration of its equipment.

QA 700, Par. 4.2 (Equipment Maintenance and Calibration) covers this
150-22 - 5.6.1 - QA 700, Paragraph 4.1 (Test and Evaluation Tools) is appropriate.

NOTE Such a program should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.

NVLAP Note: See Annex B for requirements for the implementation of traceability policy in NVLAP-accredited laboratories.

5.6.2 Specific requirements

5.6.2.1 Calibration

5.6.2.1.1

N/A a) For calibration laboratories, the program for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (*Système international d'unités*).

A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute.

N/A b) When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability.

N/A c) The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).

NOTE 1 Calibration laboratories fulfilling the requirements of this handbook are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this handbook, for the calibration concerned, is sufficient evidence of traceability of the calibration data reported.

NOTE 2 Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).

NOTE 3 Calibration laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute.

NOTE 4 The term "identified metrological specification" means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

NOTE 5 When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfill the properties of primary standards for the realization of SI units.

NOTE 6 Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located.

NOTE 7 If a calibration laboratory wishes or needs to obtain traceability from a national metrology institute other than in its own country, this laboratory should select a national metrology institute that actively participates in the activities of BIPM either directly or through regional groups.

NOTE 8 The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability.

N/A **5.6.2.1.2** There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

N/A a) the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;

N/A b) the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

N/A c) Participation in a suitable program of interlaboratory comparisons is required where possible.

5.6.2.2 Testing

N/A **5.6.2.2.1** For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.

NOTE The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed.

N/A **5.6.2.2.2** Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).

150-22 - 5.6.2 - QA 700, Par. 4.1 (Test and Evaluation Tools) covers this.

5.6.3 Reference standards and reference materials

5.6.3.1 Reference standards

OK a) The laboratory shall have a program and procedure for the calibration of its reference standards.

QA 700, Paragraph 4.2 (Equipment Maintenance and Calibration) covers this item.

OK b) Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1.

QA 700, Paragraph 4.2 (Equipment Maintenance and Calibration) covers this item.

OK c) Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

QA 700, Paragraph 4.2 (Equipment Maintenance and Calibration) covers this item.

5.6.3.2 Reference materials

OK Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

QA 700, Paragraph 4.2 (Equipment Maintenance and Calibration) covers this item.

5.6.3.3 Intermediate checks

OK Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.

QA 700, Paragraph 4.2 (Equipment Maintenance and Calibration) covers this item.

5.6.3.4 Transport and storage

OK The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

QA 700, Par. 4.1 (Test and Evaluation Tools) and QA 600, Par. 4.11 (Tool and Equipment Use cover this item.
150-22 - 5.6.3 - QA 700, Par. 4.2 (Equipment Maintenance and Calibration) covers this item

NOTE Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.

5.7 Sampling

5.7.1

OK a) The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration.

QA 600, Par. 4.6 (Sampling) covers this.

OK b) The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.

QA 600, Par. 4.6 (Sampling) covers this
150-22 - 5.7.1 - QA 600, Par. 4.6 (Sampling) covers this

NOTE 1 Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g., forensic analysis), the sample may not be representative but is determined by availability.

NOTE 2 Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information.

OK **5.7.2** Where the customer requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.

QA 600, Par. 4.6 (Sampling) covers this.
150-22 - 5.7.2 - QA 611 (Voting System Test Process), Par. 5.8 (Report Finalization and Submission), Sub-paragraph 5.8.1 (Test Engineer) contains a Note that covers this topic.

OK **5.7.3** The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.

QA 600, Par. 4.6 (Sampling) covers this.
150-22 - 5.7.2 - QA 611 (Voting System Test Process), Par. 5.8 (Report Finalization and Submission), Sub-paragraph 5.8.1 (Test Engineer) contains a Note that covers this topic.

5.8 Handling of test and calibration items

OK **5.8.1** The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items,

including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.

QA 802 (Receiving), Par. 5.6 (Receiving Inspection) covers this item along with QA 701 (Test and Evaluation Tool Control), Par. 5.1 (Initial Receipt of Test and Evaluation Tool).
150-22 - 5.8.1 -QA 500, Par. 4.2 (Accommodations) states that "The Accommodations shall be adequate to provide separation between multiple products under simulteneous test or evaluation."

5.8.2

OK a) The laboratory shall have a system for identifying test and/or calibration items.

QA 701 (Test and Evaluation Tool Control), Par. 5.1 (Initial Receipt of Test and Evaluation Tool) contains a statement under Par. 5.1.2 (Quality Document Control) to the effect that "Uniquely identify and log into Test Tools Distribution Log, Appendix I, located on the server."

OK b) The identification shall be retained throughout the life of the item in the laboratory.

QA 900, Par. 4.3 (Quality Records) covers this topic.

OK c) The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents.

QA 600, Par. 4.5 (Test and Evaluation Process) is appropriate.

OK d) The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.

QA 701 (Test and Evaluation Tool Control), Par. 5.1 (Initial Receipt of Test and Evaluation Tool) contains statements under Par. 5.1.2 (Quality Document Control) to cover this item.
150-22 - 5.8.2 - QA 600, Par. 4.5 (Test and Evaluation Process), 4th sub-paragraph covers this topic.

5.8.3

OK a) Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded.

QA 802 (Receiving), Appendix II, Receiving Inspection Report and IN 802-II cover this topic.

OK b) When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the customer for further instructions before proceeding and shall record the discussion.

QA 802 (Receiving), Appendix II, Receiving Inspection Report and IN 802-II cover this topic.
150-22 - 5.8.3 - QA 301 (Test and Evaluation Evidence Control), Paragraphs 8.1 (Employee in Possession of Test or Evaluation Evidence) and 9.3 (Disposition of Archived Test or Evaluation Evidence) are appropriate for this topic.

5.8.4

OK a) The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation.

QA 500 (Policy on Facilities), Par. 4.2 (Accommodations) is appropriate.

OK b) Handling instructions provided with the item shall be followed.

QA 802 (Receiving), Par. 5.5 (Receiving of InfoGard Purchased Test and Evaluation Materials) and Par. 5.6 (Receiving Inspection) cover this item.

OK c) When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

QA 301, Par. 8.1 (Employee in Possession of Test orEvaluation Evidence), sub-paragraph c) states that the employee will "maintain , monitor, and record environmental conditions for the test or evaluation hardware, if required."

OK d) Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

QA 301, Par. 8.1 (Employee in Possession of Test orEvaluation Evidence), sub-paragraph d) states that the employee will "Store and secure the test or evaluation hardware, as required, to protect its condition and intgerity."

NOTE 1 Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting processes.

NOTE 2 A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, should be provided to those responsible for taking and transporting the samples.

NOTE 3 Reasons for keeping a test or calibration item secure can be for reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later.

5.9 Assuring the quality of test and calibration results

5.9.1

OK a) The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.

QA 700. Par. 4.1 (Test and Evaluation Tools) covers this in sub-paragraph #1.

OK b) The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.

QA 700. Par. 4.1 (Test and Evaluation Tools) and Par. 4.2 (Equipment Maintenance and Calibration) covers this.

OK c) This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

QA 700. Par. 4.2 (Equipment Maintenance and Calibration) covers this

OK 1) regular use of certified reference materials and/or internal quality control using secondary reference materials;

N/A 2) participation in interlaboratory comparison or proficiency-testing programs;

N/A 3) replicate tests or calibrations using the same or different methods;

OK 4) retesting or recalibration of retained items;

N/A 5) correlation of results for different characteristics of an item.

NOTE The selected methods should be appropriate for the type and volume of the work undertaken.

OK♦ **5.9.2** Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.

QA 700. Par. 4.1 (Test and Evaluation Tools) covers this. Also, QA 600, Par. 4.11 (Tool and Equipment Use) cover this topic.
150-22 - 5.9 - QA 611, Par. 5.8 (Report Finalization and Submission) , Sub-paragraph 5.8.1 (Test Engineer) through sub-paragraph 5.8.7 (Quality Document Control) are appropriate for this requirement.

5.10 Reporting the results

5.10.1 General

OK a) The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

VSP 114, 2 Scope,
The bullets in the Scope section identify a good coverage. Needs to consider specifying in test method presentation in report

OK b) The results shall be reported, usually in a test report or a calibration certificate (see Note 1), and shall include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.

QA 600, 4.7 Test and Evaluation Reporting

C c) In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the customer shall be readily available in the laboratory which carried out the tests and/or calibrations.

(150-22) 5.10.4 Reports intended for use only by the customer shall meet customer-laboratory contract obligations and be complete, but need not necessarily meet all VSS-2002 requirements. Information required to reproduce the test but not included in the test report shall be kept by the laboratory as part of the testing records.
QA 611. Reference to identifying the report as out of the scope of accreditation. InfoGard has had the practise that such reports are under their Non-Disclaimer Agreement and restricted to use by the customer only.

NOTE 1 Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively.

NOTE 2 The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this handbook are met.

5.10.2 Test reports and calibration certificates

Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:

OK	a)	a title (e.g., "Test Report" or "Calibration Certificate");
		"National Test Report" Template
X	b)	the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;
		Needs to be added
OK	c)	unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;
		Document control ID. Need to add "n page of m pages" style item
OK	d)	the name and address of the customer;
		Second page behind title page
OK	e)	identification of the method used;
		VSP 114, 4.6 'a)' Test Engineer. Type in copy reviewed 'a)' is between e) and f)
C	f)	a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;
		"condition" needs to be added.
N/A	g)	the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration;
OK	h)	reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;
		Included in the assertion database detail records. Not expected to be significant item in current test plans.
N/A	i)	the test or calibration results with, where appropriate, the units of measurement;
X	j)	the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;
		Shown report from FIPS 140-2 program conducted by InfoGard. Needs to be added to report template
X	k)	where relevant, a statement to the effect that the results relate only to the items tested or calibrated.
		Needs to be added

NVLAP Note: NVLAP defines the person(s) who authorizes the test report or calibration certificate as the Approved Signatory (see 1.5.2).

NOTE 1 Hard copies of test reports and calibration certificates should also include the page number and total number of pages.

NOTE 2 It is recommended that laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.

5.10.3 Test reports

5.10.3.1 In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:

OK a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;

OK b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;

OK c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit;

OK d) where appropriate and needed, opinions and interpretations (see 5.10.5);

OK e) additional information which may be required by specific methods, customers or groups of customers.

5.10.3.2 In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:

OK a) the date of sampling;

OK b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);

OK c) the location of sampling, including any diagrams, sketches or photographs;

OK d) a reference to the sampling plan and procedures used;

OK e) details of any environmental conditions during sampling that may affect the interpretation of the test results;

OK f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

5.10.4 Calibration certificates

5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results:

N/A a) the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results;

N/A b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;

N/A c) evidence that the measurements are traceable (see Note 2 in 5.6.2.1.1).

5.10.4.2

N/A a) The calibration certificate shall relate only to quantities and the results of functional tests.

N/A b) If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.

N/A c) When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.

N/A d) When statements of compliance are made, the uncertainty of measurement shall be taken into account.

N/A **5.10.4.3** When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.

N/A **5.10.4.4** A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. This requirement may be superseded by legal regulations.

5.10.5 Opinions and interpretations

OK When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.

NOTE 1 Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65.

NOTE 2 Opinions and interpretations included in a test report may comprise, but not be limited to, the following:

i) an opinion on the statement of compliance/noncompliance of the results with requirements;

ii) fulfillment of contractual requirements;

iii) recommendations on how to use the results;

iv) guidance to be used for improvements.

NOTE 3 In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the customer. Such dialogue should be written down.

5.10.6 Testing and calibration results obtained from subcontractors

OK a) When the test report contains results of tests performed by subcontractors, these results shall be clearly identified.

OK b) The subcontractor shall report the results in writing or electronically.

OK c) When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.

5.10.7 Electronic transmission of results

OK In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this handbook shall be met (see also 5.4.7).

5.10.8 Format of reports and certificates

OK The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.

NOTE 1 Attention should be given to the layout of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader.

NOTE 2 The headings should be standardized as far as possible.

5.10.9 Amendments to test reports and calibration certificates

OK a) Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement:

"Supplement to Test Report [or Calibration Certificate], serial number . . . [or as otherwise identified]," or an equivalent form of wording.

OK	b)	Such amendments shall meet all the requirements of this handbook.
OK	c)	When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.

Annex A (normative)

Referencing NVLAP accreditation

A.1 Conditions for referencing the NVLAP term, logo, and symbol

The term *NVLAP* and the NVLAP logo are registered marks of the Federal Government, which retains exclusive rights to control the use thereof. Permission to use the term and symbol (NVLAP logo with approved caption) is granted to NVLAP-accredited laboratories for the limited purpose of announcing their accredited status, and for use on reports that describe only testing or calibration within the scope of accreditation. NVLAP reserves the right to control the quality of the use of the NVLAP term, logo, and symbol.

In order to become and remain accredited, laboratories shall comply with the following conditions pertaining to the use of the term *NVLAP*, the NVLAP logo, and NVLAP symbol. Failure to comply with these conditions may result in suspension or revocation of a laboratory's accreditation.

OK **a)** An applicant laboratory that has not yet achieved accreditation may make reference to its applicant status. If the NVLAP Lab Code is used, it shall be accompanied by a statement accurately reflecting the laboratory's status. An applicant laboratory shall not use the NVLAP term, logo or symbol in a manner that implies accreditation.

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic.

OK **b)** The laboratory shall have a policy and procedure for controlling the use of the term *NVLAP* and the NVLAP symbol.

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

OK **c)** The term and/or symbol shall not be used in a manner that brings NVLAP into disrepute or misrepresents a laboratory's scope of accreditation or accredited status.

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

OK **d)** When the term *NVLAP* is used to reference a laboratory's accredited status, it shall be accompanied by the NVLAP Lab Code.

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

OK **e)** When the NVLAP symbol is used to reference a laboratory's accredited status, it shall be comprised of the NVLAP logo and the NVLAP Lab Code in an approved caption. The caption shall appear below and in close proximity to the logo. The following captions have been approved by NVLAP:

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

- "For the scope of accreditation under NVLAP Lab Code 000000-0"

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

- "NVLAP Lab Code 000000-0".

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

See Annex A of NIST Handbook 150 for examples of the logo with captions.

f) When the NVLAP symbol is used, the form of the NVLAP logo must conform to the following guidelines:

OK 1) The logo shall stand by itself and shall not be combined with any other logo, symbol, or graphic.

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

OK 2) The aspect ratio (width to height) shall be 2.25 to 1.

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

OK 3) The logo and caption shall be of a size that allows the caption to be easily read. The size of the caption shall not exceed the size of the logo itself.

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

OK 4) The logo shall appear in black, blue, or other color approved by NVLAP, and may be filled or unfilled. In the case of a filled logo, the same color shall be used for the outline and the fill.

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

OK **g)** The name of at least one Approved Signatory shall appear on a test or calibration report that displays the NVLAP symbol or references NVLAP accreditation. A computer-generated report may have the Approved Signatory's name printed along with the test or calibration results, as long as there is evidence that there is a system in place to ensure that the report cannot be generated without the review and consent of the Approved Signatory. There may be legal or contractual requirements for original signatures to appear on the report.

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

h)

OK 1) When the term and/or symbol are used on test or calibration reports, such use shall be limited to reports in which some or all of the data are from tests or calibrations performed by the laboratory under its scope of accreditation.

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

OK 2) A test or calibration report that contains both data covered by the accreditation and data not covered by the accreditation shall clearly identify the data that are not covered by the accreditation.

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

OK 3) The report must prominently display the following statement at the beginning of the report: "This report contains data that are not covered by the NVLAP accreditation."

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

i)

OK 1) When the term and/or symbol are used on test or calibration reports that also include work done by subcontracted laboratories, such use shall be limited to reports in which some or all of the data are from tests or calibrations performed by the laboratory under its scope of accreditation.

QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

OK 2) A test or calibration report that contains both data covered by the accreditation and data provided by a subcontractor shall clearly identify the data that were provided by the subcontracted laboratory.

		QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic
	OK	3) The report must prominently display the following statement at the beginning of the report: "This report contains data that were produced under subcontract by Laboratory X." If the subcontracted laboratory is accredited by NVLAP, then its Lab Code should also be stated.
		QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic
	OK	4) If the subcontracted laboratory is accredited by a body other than NVLAP, then the name of the accreditation body and the laboratory's number or other unique identifier should also be stated. If the subcontracted laboratory is not accredited, then this must be stated.
		QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic
OK	**j)**	Each test or calibration report bearing the term and/or symbol shall include a statement that the report must not be used by the client to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the Federal Government.
		QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic
OK	**k)**	When used in a contract or proposal, the term and/or symbol shall be accompanied by a description of the laboratory's scope of accreditation and current accreditation status.
		QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic
OK	**l)**	Laboratories shall not use the terms *certified* or *registered* when referencing their NVLAP accreditation or conformance to ISO/IEC 17025 requirements. The correct term is *accredited*.
		QA 101, Procedure on Use of the NVLAP Term and Logo covers this topic

Annex B (normative)

Implementation of traceability policy in accredited laboratories

B.1 Policy overview

It is a fundamental requirement that the results of all accredited calibrations and the results of all calibrations required to support accredited tests shall be traceable to the SI (the International System of Units) through standards maintained by the National Institute of Standards and Technology (NIST) or other internationally recognized national metrology institutes (NMIs). NIST Handbook 150 (and ISO/IEC 17025) details the specific requirements for traceability to be met by testing and calibration laboratories. This annex provides guidance as to how these requirements may be met and how traceability of measurement can be assured by an accredited laboratory.

Internationally recognized NMIs are those that are signatory to the Comité International des Poids et Mesures (CIPM) Mutual Recognition Arrangement (MRA) titled “Mutual recognition of national measurement standards and of calibration and measurement certificates issued by national metrology institutes” and that have the necessary calibration services listed in Appendix C of the MRA, Calibration and Measurement Capabilities (CMC). For more details on the CIPM MRA and the CMC database, please see <http://www.bipm.org/en/convention/mra/> or visit the NVLAP web site.

B.2 General

OK a) Laboratories shall be able to demonstrate proper use of traceable standards and test and measurement equipment by competent laboratory personnel in a suitable environment in performing the tests for which accreditation is desired or held. This demonstration will include the determination of the appropriate measurement uncertainty.

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

OK b) Calibration certificates received by NVLAP-accredited testing and calibration laboratories with new or recalibrated equipment shall meet the requirements of ISO/IEC 17025. The certificates must include the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof.

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

Note to assessor: The NVLAP assessor(s) must, for each measurement parameter, indicate which method the laboratory has employed to achieve traceability. Select from B.3.1, B.3.2, B.3.3, B.3.4, or B.3.5 below. If B.3.4 or B.3.5 is selected, supporting documentation is also required as indicated.

B.3 Demonstration of traceability

OK **B.3.1** NVLAP-accredited laboratories may submit appropriate physical standards and test and measurement equipment directly to NIST or, when appropriate, to another national metrology institute. Accredited laboratories may obtain certified reference materials from NIST (called Standard Reference Materials under copyright) or from another national metrology institute. Use of a national metrology institute other than NIST shall be documented and will be assessed by NVLAP.

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

OK **B.3.2** Testing laboratories that perform calibrations only for themselves do not need to be accredited as calibration laboratories. Calibration laboratories that perform specific calibrations only for themselves to support their accredited services do not need to be accredited for those calibrations. For the purpose of assuring traceability, an accredited laboratory may calibrate its own equipment if the appropriate requirements of NIST Handbook 150 have been met.

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

OK **B.3.3** NVLAP-accredited laboratories that do not demonstrate traceability as described in B.3.1 or B.3.2, shall use accredited calibration laboratory services wherever available. Accredited calibration laboratories are those accredited by NVLAP or by any accrediting body with which NVLAP has a mutual recognition arrangement. A listing of NVLAP-accredited calibration laboratories and of accreditation bodies with which NVLAP currently has agreements is available from NVLAP.

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

OK **B.3.4** If a NVLAP-accredited laboratory submits physical standards or test and measurement equipment to a calibration service provider that is not accredited by NVLAP or by an accrediting body with which NVLAP has a mutual recognition arrangement, the laboratory shall:

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

OK a) document that an appropriate accredited calibration service provider is not available;

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

OK b) audit the claim of traceability of the provider of the calibration service and document the following areas related to the calibration and claim of traceability of its standards and test and measurement equipment:

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

OK 1) information regarding assessment of the quality system used by the calibration service provider,

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

OK 2) the calibration procedure(s) used by the calibration service provider,

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

OK 3) the physical standards or other test and measurement equipment used by the calibration service provider (including evidence of traceability to standards maintained by NIST or an appropriate national metrology institute and copies of relevant calibration certificates),

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

OK 4) information regarding the calibration intervals of relevant standards or other test and measurement equipment,

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

OK 5) the environmental conditions of the laboratory,

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

OK 6) the method(s) by which uncertainties are determined (e.g., Guide to the Expression of Uncertainty in Measurement (GUM), and

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

OK 7) the relative uncertainties achieved at all steps of the process;

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

OK c) pursue the traceability chain until traceability to appropriate stated references is completely validated, when a calibration service provider submits physical standards and/or test and measurement equipment used in the calibration to another laboratory(s) not accredited by NVLAP;

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

OK d) enter the audit documentation, including all findings of nonconformance and resolutions of those findings, into the laboratory's quality management record-keeping system.

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

NOTE An on-site visit to the provider of the calibration service is encouraged, but is not required as long as the information listed above is obtained and otherwise verified. Self-declaration of compliance to ISO/IEC 17025 or other relevant standards by a calibration service provider is not acceptable evidence of verification of traceability. Citation of a NIST Test Number by the calibration service provider likewise is not acceptable evidence of verification of traceability.

OK **B.3.5** If traceable calibration services are not available or appropriate, laboratories may demonstrate comparison to a widely used standard that is clearly specified and mutually agreeable to all parties concerned, particularly in measurements where NIST does not maintain a U.S. national standard. For example, NIST does not maintain a standard for all hardness testing scales. There are several widely used commercial standards available for hardness. However, these standards may not all give equivalent measurement results; therefore, it is important to specify which standard is used and to obtain agreement among all parties involved that the choice made is acceptable.

QA 700 is the Policy on Measurement Traceability and Calibration which covers this item.

NIST HANDBOOK 150 CHECKLIST
COMMENTS AND NONCONFORMITIES

Instructions to the Assessor: Use this sheet to document comments and nonconformities. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and nonconformities with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

Item No.	*C or X*	*Comments and/or Nonconformities*
4.3.1	X	Two documents were reviewed; both had the same header information but contained different information (QA201 procedure).
5.4.1.a	X	Not all test methods include sufficient detail in procedures and consideration for factors in 5.1.1, 5.4.1, and 5.4.4. Some specific examples are Usability and the Accuracy test methods.
5.4.1.d	X	Need procedures for obtaining record of acceptance from client when a deviation to a test method is documented and authorized.
5.4.2.a	X	Test methods were adopted from Common Criteria methods but write-ups do not appear to have completed final editing to apply to voting systems applications and criteria besides the original security emphasis
5.4.2.b	X	Some of the standard test methods derived from Voting System standards need supplemental procedural details such as the setup of test vehicle for HAVA 301 requirements, criteria for ballot layout in Accuracy and Reliability testing, timing/sampling of voting in the 48 environmental testing, and the need to provide additional specification of table height in the accessibility standards.
5.4.3a	X	Same as observation on 5.4.1.a except applied to laboratory developed methods.
5.4.4.a	X	Need to provide for identifying in test plans and reports any test methods included in the test campaign that are outside of the laboratory's scope of accreditation.
5.4.5.2 a & b	X	Test methods have not been validated so records of validation are missing
5.10.2b	X	Location where tests were carried if different than the address of the lab
5.10.2.f	C	Need to add "condition" of equipment
5.10.2.j	X	Authorization block for report needs to be added
5.10.2.k	X	Statement that results only apply to identified equipment under test
5.10.1c	C	